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Participation in Research Studies: Factors Associated with Failing to Meet Minority Recruitment Goals

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Abstract

Purpose: To determine the recruitment goals that investigators set for racial/ethnic minorities and the factors associated with failure to meet those goals.

Methods: 440 Principal Investigators (PIs) conducting clinical research funded by the National Heart, Lung, and Blood Institute (NHLBI) in 2001 completed a mailed survey providing their minority recruitment goals and enrollment data for their most recent NHLBI-funded study.

Results: Ninety two percent of PIs set goals for African Americans, 68% for Hispanics, 55% for Asian Americans, 35% for Native Hawaiians/Pacific Islanders, and 23% of PIs set recruitment goals for American Indians/Native Alaskans. Among those PIs who did set minority recruitment goals, the mean goal for the recruitment of African Americans was 31%, 16% for Hispanics, and 9% for Asian Americans. Twenty seven percent of PIs failed to meet their recruitment goals for African Americans, 23% for Asian Americans, and 23% for Hispanics. After adjusting for multiple investigator and trial characteristics, the type of study (OR 1.8, 95% CI 1.2, 3.4 for observational vs. phase III trial) completion of study enrollment (OR 2.0, 95% CI 1.2, 3.4), and PI identification of a larger number of major barriers to participation (OR 1.8, 95% CI 1.1, 3.0) were all associated with failure to meet recruitment goals for African Americans. However, no factors were consistently associated with failure to meet recruitment goals across different racial/ethnic groups.

Conclusions: Investigators often do not set recruitment goals for some racial/ethnic groups. Factors associated with failure to meet recruitment goals vary in the recruitment of different minority groups.

Keywords

minorities; patient selection; research personnel; biomedical research

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Introduction

Racial and ethnic minority groups have been underrepresented in clinical research compared to their burden of disease and their representation in the U.S. population [1-3]. This pattern has spurred research on potential barriers to minority research participation [4-9], often focusing on the perceptions of potential study participants by surveying minority patients in a wide variety of clinical and community settings [5,6,9-12]. While potential study participants are valuable sources of information on barriers to minority recruitment, investigators can also provide valuable information as the coordinators of recruitment and enrollment. Previous assessments of researchers' opinions about minority recruitment have identified barriers such as a perception of lower interest in clinical trials among minority patients and a lack of investigator confidence in explaining clinical trials in culturally appropriate terms [13].

Despite the perception of barriers to minority recruitment, we know very little about the recruitment goals that investigators set for racial and ethnic minority groups and whether they meet these goals. Investigators' minority recruitment goals likely parallel their intentions to include diverse study samples in their research. The National Institutes of Health (NIH) requires investigators to report recruitment goals for minorities to demonstrate adequate minority representation in clinical studies [14]. Yet, there is a dearth of peer-reviewed data not only on investigators' minority recruitment goals, but also on the actual rates of minority enrollment and the various factors that may influence those rates [15,16]. Investigator surveys are essential tools for assessing recruitment goals and investigators' failure rates in meeting their goals. We conducted a nationwide survey of federally funded Principal Investigators (PIs) to assess 1) the goals they set for minority recruitment, 2) the percentage of PIs that failed to reach their goals, and 3) whether PI and study characteristics and PIs' perceptions of minority recruitment are associated with their failure to meet minority recruitment goals.

Methods

Study Population

The study population was composed of PIs conducting research funded by the National Heart, Lung, and Blood Institute (NHLBI). We received a list from the NHLBI of all PIs who had active NHLBI grants in the FY 2001 involving research with human subjects. This list comprised a total of 894 researchers. We initially excluded 177 names from the sample including 23 names that were duplicates, those holding Fellowship or Training awards (n=14), K (career) Awards (n=84) and 56 investigators not involved with the recruitment of human subjects (e.g. R13 conference awards). We compared the sample to project abstracts in the CRISP (Computer Retrieval of Information on Scientific Projects) database, a searchable database of NIH-funded biomedical research projects, maintained by the NIH Office of Extramural Research. We excluded 34 additional studies led by PIs that were conducting research only on animals or non-living human subjects. We mailed the survey to the remaining 683 NHLBI PIs.

Survey

The 38-item mailed survey assessed the attitudes and experiences of PIs in their recruitment of women and minorities for clinical research studies. The questionnaire included items on perceived barriers to minority enrollment, study recruitment goals and actual enrollment by both race and gender, and the recruitment sites and methods used by investigators. Some items were devoted to study characteristics such as length of funding and classification of study. The survey also included questions about PIs' professional and demographic characteristics.

Measures

We asked PIs to tell us how many total subjects they expected to enroll in their most recent NHLBI-funded study. We also asked, "Thinking of that same study, what were your *recruitment goals* for each of the following racial/ethnic groups?" These groups included 1) Caucasian/White Americans, 2) Blacks/African Americans, 3) Asian Americans, 4) American Indians/Native Alaskans, and 5) Native Hawaiians/Pacific Islanders. PIs were asked for their recruitment goals for Hispanics/Latinos in a separate item to correspond with reporting requirements used in NIH grant applications and progress reports. All minority recruitment goals were expressed as a proportion (%) of the overall recruitment goal for the entire study population. To determine the actual enrollment proportions comprised by each racial/ethnic group, respondents were asked, "In that same study, what percentage of those *actually enrolled* were in each of the following racial/ethnic groups?". Responses were expressed as proportions (%) of the overall enrollment for the entire study population. Again, separate responses were required for each racial/ethnic group.

Dependent Variables

We approached our main outcomes in the following manner. First, we determined whether PIs set recruitment goals for each racial/ethnic group. Those who responded to an item asking for recruitment goals for a particular racial/ethnic group with a "0" were categorized as not having set any recruitment goals for that group. Those responding with positive integers were categorized as having set recruitment goals for that group. Respondents with missing values for these items were excluded from these analyses.

Among those PIs who did set goals and reported completed study enrollment, we assessed whether or not they failed to reach their minority recruitment goals based on a comparison of their recruitment goals with their reported enrollment proportions. Using the total number planned for recruitment and the total enrollment number, we calculated the absolute numbers for recruitment goals and the absolute numbers for enrollment of members of each racial/ethnic group (e.g. absolute number of whites targeted for recruitment= targeted proportion of sample represented by whites X total number targeted for recruitment; absolute number of whites enrolled= proportion of study sample composed by whites X total number of enrolled subjects). Among PIs failing to meet recruitment goals, we then calculated the mean proportion of the recruitment goal reached by PIs based on the absolute numbers for recruitment goals and enrollment for each racial/ethnic group (e.g. proportion of recruitment goal for whites reached= number of whites enrolled / number of whites targeted for recruitment). Respondents who did not set goals or those with missing values for these items were excluded from this portion of the analysis.

In defining the failure to meet recruitment goals based on actual percentages, we did not account for some uncertainty in the reported enrollment proportions. Because each PI was reporting based on his/her own most recent NHLBI-funded study, the respondents provided minority enrollment proportions for studies of varying sample sizes and for studies at different stages of recruitment. Recognizing that the reported enrollment proportions represent random variables resulting from the underlying recruitment process, we calculated an exact 95% upper bound for the enrollment proportion represented by each racial/ethnic group for all PIs setting recruitment goals whether or not they had completed study enrollment [17,18]. We used the total number of enrolled subjects at the time of the survey and the reported proportion of enrolled subjects from an individual racial/ethnic group to calculate an exact 95% upper bound for the enrollment proportion represented by that group. Then we compared the recruitment goal to the 95% upper bound for the enrollment proportion to determine if a PI failed to meet his/her recruitment goals [17,18]. For example, if a PI reported a recruitment goal of 20% for African Americans and the 95% upper bound for the reported enrollment proportion

represented by African Americans was 15% (recruitment goal > 95% upper bound for enrollment proportion), then that PI was classified as "having failed to meet his/her recruitment goal" for African Americans for that study. Conversely, if a PI set a recruitment goal of 15% for African Americans and the 95% upper bound for the enrollment proportion represented by African Americans was 20% (recruitment goal ≤ 95% upper bound for enrollment proportion), then that PI was classified as "not having failed to meet his/her recruitment goal" for African Americans for that study.

Independent variables

We assessed the number of recruitment sites or methods used by PIs in their past studies. Respondents were asked to select from a list of 18 recruitment sites or methods (e.g. physician referral, registries, church/religious groups, random digit dialing). We calculated the number of recruitment sites or methods used by each respondent. Respondents provided information about study characteristics of their most recent study such as study type (e.g. observational, phase I, II, or III), contract or grant award, and year of funding. Investigator characteristics identified included age, gender, race/ethnicity, academic rank, degrees held, and total number of years of funding as a PI. Respondents were also asked about their perceptions of a set of nine potential barriers (e.g. lack of access to study population, lack of funding for recruitment, participants' distrust of research/medicine) to minority enrollment. They were asked to rate these nine barriers as "major" (4 points), "moderate" (3 points), "minor" (2 points), or "not a barrier" (1 point). A barrier score was assigned to each respondent by calculating the mean of his/her ratings for the 9 barriers. Items left blank were not included in the calculation of the barrier score.

Data Analysis

Data were analyzed using SAS version 9.1 (SAS Institute, Cary, NC). We examined baseline characteristics of the respondents and calculated the proportions of those who set recruitment goals and those who did not set recruitment goals for each minority group. We performed bivariable analyses to identify any differences between those who set minority recruitment goals and those who did not. Among those respondents who actually set minority recruitment goals, we calculated the proportions of PIs who failed to meet their minority recruitment goals based on both actual percentages reported and on our calculation of a 95% upper bound for reported enrollment proportions. We used McNemar's test for matched pairs to look for statistically significant differences between the failure rates in the recruitment of any two racial or ethnic groups. Chi-square tests were used to examine the relationships between each of the independent variables and the failure to reach the recruitment goal for each racial/ethnic group. Using a forward selection strategy to create multivariable logistic regression models, we calculated odds ratios along with 95% confidence intervals to assess the relationships between each of these independent variables and the outcome of failure to meet one's recruitment goal for each racial/ethnic group. In both the bivariable and multivariable analyses, the outcome of failure to meet recruitment goals was based on the calculation of the 95% upper bound for reported enrollment proportions.

Results

Of the 683 surveys mailed, 497 were returned by respondents. Fifty-seven (11%) of the 497 respondents were ineligible to complete the survey, because they either 1) were not the PI on any NHLBI-funded studies that were active in 2001 or 2) did not have any studies in 2001 with human subjects. After excluding the 57 ineligible respondents, our response rate was 70%.

Of the 440 survey respondents (Table 1), the majority were male and white with a mean age of 50.8 years (SD 8.2). Most respondents held a medical degree and were full professors. Clinic/

hospital-based recruitment, word-of-mouth, flyers, and physician referral were the most frequently reported recruitment methods used in recruiting all subjects (Table 2). On average, respondents reported experience with 6.7 (SD 3.5, range 0−17) different methods/sites for recruitment. Of the barriers identified by respondents, the average rating was between “minor” and “moderate” (average respondent barrier score 2.45, SD 0.62). Sixty percent of respondents reported that they had not completed enrollment for their most recent NHLBI-funded studies at the time of our survey.

Many PIs did not set recruitment goals for individual minority groups. Investigators set recruitment goals most frequently for African Americans (91%). Eighty-eight percent set goals for whites, 55% for Asians Americans, 35% for American Indians/Alaskan Natives, 22% for Native Hawaiians/Pacific Islanders, and 67% for Hispanics. Only 2.7% of respondents set goals for all of the racial/ethnic minorities. In unadjusted bivariable analyses, factors such as completed study enrollment (chi square $p<0.05$ for African Americans, American Indian/ Native Alaskan, Native Hawaiians/Pacific Islanders and $p<0.001$ for Asian Americans and Hispanics) and the use of fewer recruitment sites or methods (chi square $p<0.05$ for Asian Americans, and American Indians/Native Alaskans, Native Hawaiians/Pacific Islanders) were associated with a lower likelihood of actually setting goals for minority recruitment across multiple racial/ethnic groups.

Based on the actual proportions (%) reported among investigators both setting recruitment goals and reporting completed enrollment, the mean minority recruitment goal was highest for African Americans at 33% and lowest for Asian Americans at 10% (Table 2). Mean recruitment goals were not significantly different when including those investigators who had not yet completed enrollment (data not shown). Respondents were more likely to fail to reach their recruitment goals for African Americans, Asian Americans, and Hispanics and when compared to whites (McNemar's p-value < 0.05 in pairwise comparisons). On average, investigators reached larger proportions of their recruitment targets for whites compared to the proportions of recruitment targets reached for the racial/ethnic minority groups (Table 2). The recruitment and enrollment figures for Pacific Islanders/Native Hawaiians and American Indians/Alaskan Natives were not included in these calculations because so few respondents set recruitment goals for these subgroups.

Additional analyses were based on the use of the calculated 95% upper bound for investigators’ reported enrollment proportions to define failure to meet minority recruitment goals among all PIs, regardless of completion of enrollment. Using this definition for our outcome, the mean minority recruitment goal was highest for African Americans at 31% and lowest for Pacific Islanders/Native Hawaiians at 3% (Figure). Respondents were least successful at reaching their minority recruitment goals for African Americans (26.7% failed to meet recruitment goals) and most successful with the recruitment of American Indians/Native Alaskans with a failure rate of 18.6% (Figure). Using McNemar's test in pairwise comparisons, we found that failure rates in meeting recruitment goals for African Americans were significantly higher when compared to the recruitment of both whites and Asian Americans (data not shown).

Unadjusted bivariable analyses identified those variables associated with the failure to meet recruitment goals for each group (Table 3). These factors varied across the different racial/ ethnic groups. Likewise, multivariable regression analyses confirmed the independent association of these factors with failing to meet minority recruitment goals. These factors also varied across minority groups in multivariable analyses (Table 4). The investigators who had completed study enrollment, were conducting an observational study (vs. phase III trials), or identified a larger number of major barriers were more likely to fail to meet their minority recruitment goals for African Americans in the adjusted analysis. Conversely, having greater than 20 years of funding as a PI was associated with a lower likelihood of failure to meet

minority recruitment goals for African Americans. In the recruitment of Asian Americans, PIs conducting observational studies and phase I or II trials were less likely to reach their recruitment goals when compared to those respondents conducting phase III trials. None of the factors that we assessed was independently associated with failure to meet recruitment goals for Hispanics. Multivariable analyses were not performed for the recruitment of American Indians/Native Alaskans or Native Hawaiians/Pacific Islanders due to the small number of respondents setting goals for both these groups.

Discussion

In our national survey of PIs, we found that many respondents did not set goals for one or more racial/ethnic minority groups. Those PIs who did set goals for the racial/ethnic minority groups reported both a wide range of goals and varying rates of failure to reach their goals for each minority group. We assessed multiple factors such as the number of recruitment methods or sites used, PI perceptions of recruitment barriers, and investigator and study characteristics, but none of these was consistently associated with the failure to meet minority recruitment goals across different racial and ethnic groups.

In fact, the majority of respondents did not set goals for the recruitment of smaller minority groups such as American Indians/Native Alaskans and Native Hawaiians/Pacific Islanders. However, many respondents also did not set goals for larger minority groups such as Hispanics and Asian Americans. Setting minority recruitment goals may be important to achieve *a priori* methodologic goals for the inclusion of minorities. For instance, the numbers of minority participants needed for hypothesis testing may differ greatly from the numbers needed for more exploratory analyses aimed at generating new hypotheses [19]. The large number of PIs not setting minority recruitment goals suggests that investigators may not be planning for the recruitment of some minority groups when designing their research studies.

The NIH Revitalization Act included a universal mandate for all NIH-funded researchers which broadly stipulated that trials be designed to allow for “valid analysis” of racial differences [14]. However, the NHLBI defines appropriate minority recruitment more specifically, mandating that investigators recruit underrepresented groups such that “minorities in the study population are in the same proportions as in the U.S. population having the disease entity being studied” [20]. The NHLBI guidelines even make allowances for studies focused on diseases with unknown prevalences, mandating that minorities in these studies be represented in proportions equal to their representation in the total U.S. population. If these criteria are not met, the NHLBI requires PIs seeking funding to justify why they have planned for study populations of limited diversity. Furthermore, while the adequate representation of every minority group is not mandated in every study, NHLBI guidelines state that “broad representation and diversity are strongly encouraged, even if multiple clinics and sites are needed to accomplish it”. Despite the broad NIH mandate and more specific NHLBI guidelines, many investigators in our sample did not set recruitment goals for both large and small racial/ethnic minority groups. The lack of data on investigators setting *a priori* minority recruitment goals has made past efforts to measure or define recruitment “success” very challenging [19]. Even PIs who set minority recruitment goals may have used a broad range of criteria, aside from the NIH and NHLBI guidelines, in establishing those goals. Rather than trying to apply a universal standard of “successful” or “adequate” minority recruitment, we assessed how PIs fared in reaching their own reported recruitment goals.

We reported failure to meet minority recruitment goals based on both actual recruitment proportions and a calculated 95% upper bound for enrollment proportions. The use of the 95% upper bound allowed us to control for variation in samples sizes and in the stages of subject accrual in investigators’ studies. The likelihood of PIs failing to meet minority recruitment

goals was higher compared to the proportion failing to meet goals for whites based on the use of the enrollment proportions. These same differences were less pronounced when failure to meet goals was defined by the 95% upper bound for enrollment proportions. However, use of the 95% upper bound provides a very conservative definition of failure to meet goals, essentially requiring sufficient evidence to reject the null hypothesis that the recruitment process produces at least the target proportion for the particular racial or ethnic category. We feel this approach minimizes the bias in our assessment of the outcome of failure to meet recruitment goals.

Using the 95% upper bound to define our outcome, the rate of failure to meet minority recruitment goals was near 20% in the recruitment of all racial and ethnic groups. This finding suggests that, among those PIs setting recruitment goals, investigators have difficulty reaching goals for all racial and ethnic groups, including whites. However, investigators, on average, set much higher goals for whites than for any of the racial/ethnic minority groups. While failing to reach recruitment goals for whites may or may not jeopardize the overall statistical power of a study depending on the effect size, simultaneous failure to reach comparatively smaller recruitment goals for racial/ethnic minorities may actually preclude any “valid analysis” of differences between subgroups. Therefore, failing to meet recruitment goals for all racial/ethnic groups may pose a larger challenge in either the confirmation of previously observed racial differences or the generation of new hypotheses based on racial differences.

While some factors were associated with failure to meet recruitment goals for individual racial/ethnic groups, none of these associations remained consistent across the groups. Previous research has suggested that measures of investigator and study characteristics, such as perceived barriers and the number of recruitment sites or methods, could potentially be associated with successful minority recruitment [21,22]. However, in our analysis, each of these two variables was an aggregate measure of several factors that, when considered individually, may be associated differently with success or failure in minority recruitment efforts. We did not analyze the association of individual barriers or the use of individual recruitment methods or sites with the likelihood of failure to meet minority recruitment goals. The collective effect of these factors may differ from their individual effects on PIs’ efforts to meet their minority recruitment goals. Moreover, whether analyzed individually or collectively, the impact of these factors also may not be consistent across different racial/ethnic groups because of the varying influences among different cultures. For example, among African Americans, recruitment methods such as establishing long-term community partnerships and enlisting the aid of community leaders have been successful in individual studies [23-27]. Likewise, some authors have attributed successful African American recruitment to their use of recruitment sites such as churches and barber and beauty shops [28]. However, less published data exists on the use of these recruitment methods among other minority groups such as Hispanics and Asian Americans. Because the other groups have unique cultural influences that are distinct from those of African Americans, the recruitment methods, as well as other factors that we assessed may not have the same impact in the recruitment of other racial and ethnic minorities. Future efforts may yield more specific information by focusing on minority groups individually when identifying barriers to research participation.

Our study has several limitations. First, we surveyed PIs receiving funding from a single institute of the NIH. While this group of PIs represents a broad spectrum of research interests and conducts a wide variety of research studies, their recruitment practices, perceptions of minority recruitment, and professional and study characteristics may not be representative of investigators receiving funding from other NIH institutes or other federal or non-federal agencies. However, because of the specific guidelines set forth by the NHLBI, these investigators may, in fact, be more likely to focus on increasing the diversity of their study samples. We only questioned each PI about the recruitment goals for his/her most recent

NHLBI-funded study. Though this method allowed us to determine if PIs failed to reach their minority recruitment goals for the study of interest, it may not be indicative of their recruitment experiences in other studies. We were also limited by our inability to collect detailed information on PI access to minority populations. Finally, we do not know if PIs' reported recruitment goals are congruent with the goals they were required to report in their original grant applications for the study of interest, and thus we do not have access to any justifications they may have provided in their grant applications for not planning for a diverse study sample.

Setting specific recruitment goals is important in efforts to determine minority recruitment "success" or "failure" [19], but our study shows that many PIs do not set recruitment goals for some minority groups. Of those PIs who set recruitment goals for one or more minority groups, some did not reach these goals. Because it appears that the factors associated with PIs' failures to meet their own minority recruitment goals may differ across different racial or ethnic groups, the recruitment of different minority groups may have to be assessed individually, and ultimately unique interventions may have to be specifically designed for each group.

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List of abbreviations and acronyms

NIH, National Institutes of Health; PI, Principal Investigator; NHLBI, National Heart, Lung, and Blood Institute; CRISP, Computer Retrieval of Information on Scientific Projects; SD, standard deviation; MD, Doctor of Medicine; PhD, Doctor of Philosophy; ScD, Doctor of Science; DrPH, Doctor of Public Health; EdD, Doctor of Education; DVM, Doctor of Veterinary medicine.

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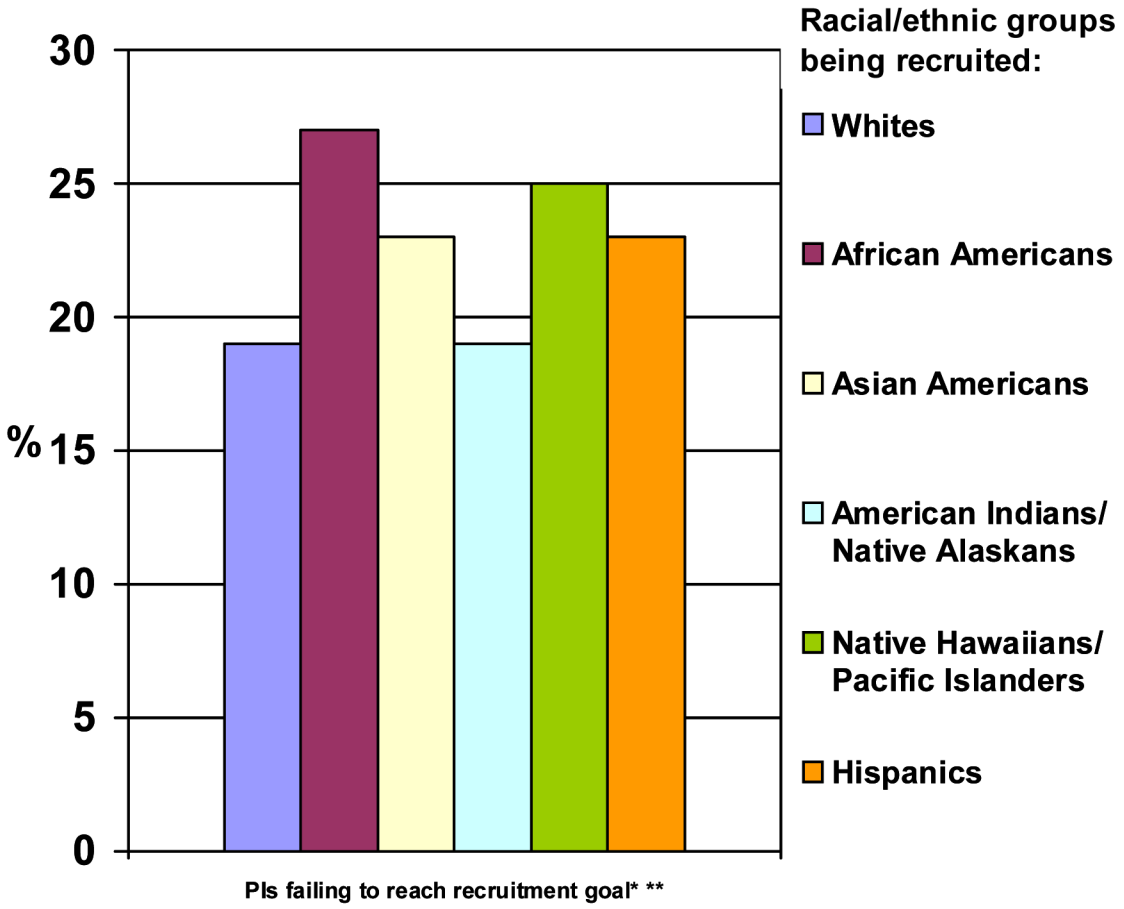

* Proportion of PIs failing to reach recruitment goals for each racial and ethnic group calculated only among those PIs setting recruitment goals for the respective racial and ethnic groups. Therefore, sample sizes (n) vary in the recruitment of the different racial and ethnic groups.
** In pairwise comparisons, McNemar's test showed significant differences ($p < 0.05$) between proportions of PIs failing to meet recruitment goals only for the comparisons of Whites vs. African Americans, Whites vs. Asian Americans, and African Americans vs. Asian Americans.

Figure.
For each racial or ethnic group being recruited, the proportion of PIs failing to meet recruitment goals based on 95% upper bound.

Table 1

Baseline characteristics

Investigator and Study Characteristics [*]	**Mean ± SD (yrs.)**
Age (n=418)	**50.8 ± 8.2**
	N (%)
Gender (n=428)	
Male	319 (75)
Female	109 (25)
Race (n=425)	
White	395 (93)
Non-white	30 (7)
Hispanic Ethnicity (n=429)	
Non-Hispanic	416 (97)
Hispanic	13 (3)
Academic Rank (n=430)	
Full Professor	270 (63)
Associate Professor	116 (27)
Other[†]	44 (10)
Degrees held (n=434) [‡]	
MD	253 (58)
PhD/Other doctoral degrees	180 (41)
Other	1 (<1)
Number of years since first funded as PI (n=435)	
<5	59 (14)
5−10	113 (26)
11−20	161 (37)
> 20	102 (23)
Type of study (n=430)	
Observational	190 (44)
Phase I or II clinical trial	37 (9)
Phase III clinical trial	65 (15)
Other	138 (32)
Completed study enrollment (n=428)	
Yes	170 (40)
No	258 (60)
Was any portion of your most recently NHLBI-funded study a contract? (n=431)	
Yes	36 (8)
No	395 (92)
Current year of funding for most recent NHBLI study (n=431)	
1st or 2nd	165 (38)
3rd or 4th	177 (41)
5th, 6th, or Completed	89 (21)

[*] Total number for each variable may be less than total number of respondents (N=440) due to some missing values (individual response rates to these items ranged from 95%−99%)

[†] "Other" category includes "Instructor", "Assistant Professor", and "not academically affiliated"

[‡] "Degrees held — "MD" includes all PIs having at least an MD (e.g. MD, MD/PhD); "Other doctoral degrees" includes ScD, DrPH, EdD, DVM; "Other" includes PIs holding neither MD or a doctoral degree.

Table 2

Mean recruitment goals, proportions failing to meet recruitment goals, and mean shortfall among those failing to meet recruitment goals and reporting completed enrollment*

Ethnic group being recruited:	Mean recruitment goals** Mean % ± SD (n)	Failed to meet recruitment goals† % (n)	Proportion of recruitment goal reached among those failing to meet recruitment goals‡§ Mean % ± SD (n)
Whites	71 ± 19 (n=141)	30 (n=43)	88 ± 27 (n=41)
African Americans	33 ± 28 (n=134)	51 (n=69)	60 ± 45 (n=65)
Asian Americans	11 ± 19 (n=62)	55 (n=34)	41 ± 31 (n=34)
Hispanics	21 ± 28 (n=81)	44 (n=36)	45 ± 32 (n=32)

*Pacific Islanders/Native Hawaiians and American Indians/Native Alaskans excluded due to small numbers (n<10) setting goals for these groups among PIs with completed enrollment.

**Mean recruitment goal reported as percentage of total sample that respondent targeted for each racial/ethnic group.

†"Failure to meet goals" based on comparison of recruitment goal and enrollment of each racial/ethnic group reported as proportions.

‡"Proportion of recruitment goal for whites reached" = [number of whites enrolled] / [number of whites targeted for recruitment]

§N's vary due to some respondents reporting "0" in numerator of calculation of "proportion of recruitment target enrolled".

Table 3

Proportion of PIs failing to meet recruitment goals by investigator and trial characteristics

Investigator and Study Characteristics	% of PIs Failing to Meet Recruitment Goals for: Whites %	African Americans %	Asian Americans %	Hispanics %
Gender				
Male	16.5*	26.8	22.4	22.6
Female	30.4	27.7	25.0	23.3
Age				
31−40	29.0	23.7	28.6	27.3
41−50	20.0	31.3	26.6	27.0
51−60	16.1	24.4	19.2	17.7
> 60	22.2	25.8	17.7	19.1
Investigator race				
Caucasian/White	18.9	26.8	23.5	22.7
Non-white	31.8	32.0	20.0	28.6
Investigator ethnicity				
Hispanic	30.0	33.3	25.0	23.5
Non-Hispanic	19.4	26.9	23.1	0
Academic rank				
Associate Professor	21.6	33.0	29.2	28.0
Full Professor	16.1	23.5	16.1	17.3
Other‡	33.3	26.5	20.8	33.3
Degrees held				
MD	23.3	30.0	27.5	24.2
PhD/doctoral degree§	15.1	23.3	16.0	20.2
Other//	100.0	100.0	0	100.0
Number of yrs. since 1st funded as PI				
< 5	18.6	26.2	20.0	24.3
5−10	19.8	32.0	26.8	22.5
11−20	23.5	28.4	24.3	24.4
> 20	11.3	18.5	12.7	18.9
Type of study				
Observational	23.3	32.9	30.7†	25.2
Phase I or II trial	14.3	18.8	36.8	16.7
Phase III trial	20.0	24.5	12.1	13.5
Other	15.5	22.8	14.1	26.6
Year of funding for most recent NHLBI study				
1st-2nd	24.2	25.0	26.0	21.7
3rd-4th	16.0	25.9	19.0	22.4
> 5th or Completed	18.4	32.4	27.3	27.3
Ever been PI on contract award from NIH				
Yes	22.9	30.8	21.3	20.6
No	18.1	25.3	23.6	23.5
Was any part of your most recently NHLBI-funded study a contract?				
Yes	14.3	44.4†	29.4	25.0
No	20.1	25.2	22.3	22.8
Completed enrollment for study yet?				
Yes	20.3	33.1†	27.7	21.0
No	18.8	22.5	19.9	24.0
Mean barrier score (2.45 for entire group)				
≤ 2.45	18.8	21.3†	18.1	21.7
> 2.45	19.6	32.2	26.9	23.0
Number of recruitment sites/ methods used				
≤ 3	16.2	24.3	21.7	23.9
4−8	19.3	26.8	27.9	23.6
9−12	22.7	30.6	14.0	20.8
≥ 13	14.3	21.7	0	78.6

* p value (chi-square or Fisher's exact test) ≤ 0.01

† p value (chi-square or Fisher's exact test) ≤ 0.05

‡ "Other" category includes responses of "Instructor", "Assistant Professor", and "not academically affiliated"

§"Degrees held - doctoral degree" includes ScD, DrPH, EdD, and DVM

//"Degrees held — other" includes those respondents not holding either an MD or a PhD

Table 4

Adjusted ORs of failure to meet minority recruitment goals for individual racial/ethnic groups.*†‡

Investigator and Study Characteristics	OR	95% CI
Whites (N=329)		
Gender		
Male	ref	
Female	2.3	1.3, 4.1
African Americans (N=330)		
Completion of study enrollment		
Yes	2.0	1.2, 3.4
No	ref	
Type of trial		
Observational	1.8	1.1, 2.9
Phase III	ref	
Number of years since first funded as a PI		
< 5 yrs.	ref	
> 20 yrs.	0.4	0.2, 0.8
Mean Barrier Score		
≤ 2.45	ref	
> 2.45	1.8	1.1, 3.0
Asian Americans (N=189)		
Type of trial		
Observational	2.8	1.3, 6.1
Phase I-II	3.6	1.1, 11.7
Phase III	ref	

*Multivariable logistic regression models adjusted for all investigator and study characteristics, # of major and minor barriers identified, and # of recruitment methods or sites used. Table includes only statistically significant results.

†N for each racial/ethnic group differs due to differing numbers of respondents actually setting goals for each group and missing values

‡Multivariable analysis not performed for American Indians/Native Alaskans and Native Hawaiians/Pacific Islanders due to small sample sizes